K994211

FEB 14 2000

Attachment 11:
510(k) Summary of Safety and Effectiveness
AcuCam® Intraoral Camera Sheath

This summary of safety and effectiveness information is submitted in accordance with the requirements of 21 CFR 807.92(c).

Submitter: DENTSPLY International, Inc.
Gendex Dental X-ray Division
901 West Oakton Street
Des Plaines, IL 60018-1884

Contact Person: William T. Cousins
Area Manger Quality Assurance & Regulatory Affairs
phone: (847) 640-4924
fax: (847) 640-4970

Date Prepared: December 1, 1999

Device Name: AcuCam® Intraoral Camera Sheath

Common Name: AcuCam Sheath

Classification Name: Dental Operative Device, EIA, 872.6640

Predicate Device: Sanitherm Oral Disposable Thermometer Sheath, 510(k) K983406

Product Description: The AcuCam Intraoral Camera Sheath is a single-use device intended for use with intraoral camera systems. The intraoral camera handpiece is inserted into the sheath prior to use.

Indications for Use: The AcuCam Intraoral Camera Sheath is a single-use device intended for use with intraoral camera systems to prevent contamination of the camera handpiece with saliva and other bodily fluids.

Rationale for Substantial Equivalence

The AcuCam Intraoral Camera Sheath shares the same indications for use as the predicate device. It is manufactured with identical materials, manufacturing process, and inspection and test procedures. The difference between the AcuCam Intraoral Camera Sheath and the predicate device is the size. Biocompatibility of materials has been demonstrated.

Safety and Effectiveness Information:
There are no differences between the design or manufacture of the AcuCam Intraoral Camera Sheath and the predicate device that could affect effectiveness relative to the intended use. Biocompatibility testing was conducted in accordance with ISO 10993-5.

Conclusion:
The AcuCam Intraoral Camera Sheath was found to be substantially equivalent to the predicate device. The AcuCam Intraoral Camera Sheath is substantially equivalent to the predicate device except that the AcuCam Intraoral Camera Sheath is larger in size.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 14 2000

Mr. William T. Cousins
Area Manager
Quality Assurance & Regulatory Affairs
Dentsply International
901 West Oakton Street
Des Plaines, Illinois 60018-1884

Re: K994211
Trade Name: AcuCam® Intraoral Camera Sheath
Regulatory Class: II
Product Code: KXX
Dated: December 1, 1999
Received: December 14, 1999

Dear Mr. Cousins:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in

the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4692. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Section 3:
Intended Use

510(k) Number (if known): ~~K99424~~ K994211

Device Name: ~~DENTSPLY International, Inc.~~ AcuCam® Intraoral Camera Sheath

Indications for Use: The AcuCam® Intraoral Camera Sheath is a single-use device intended for use with the various intraoral camera systems to prevent contamination of the camera handpiece with saliva and other bodily fluids.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use _____ OR Over-the-Counter Use X
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

Clin S. Lin

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K994211